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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/612,382	07/07/2000	Dennis Bigg		8667

7590

08/26/2003

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EXAMINER

KIFLE, BRUCK

ART UNIT

PAPER NUMBER

1624

DATE MAILED: 08/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application N .

09/612,382

Applicant(s)

BIGG ET AL.

Examiner

Bruck Kifle, Ph.D.

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 5-8 and 18-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18-23 is/are rejected.
- 7) ☒ Claim(s) 5-8 and 24 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 31 6) ☐ Other: \_\_\_\_\_

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Prosecution in this case has been reopened after an appeals conference in the work group. It was agreed to include a rejection under 35 U.S.C. 112, first paragraph, before sending this case to the Board. Thus, the finality of the rejection of the last Office action is withdrawn. Claims 5-8 and 18-24 are pending in this application.

***Claim Rejections - 35 USC § 112***

Claims 18-23 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "pharmaceutically acceptable substituted camptothecin" renders the claims indefinite because one skilled in the art cannot say what the intended substituents are and where these substituents are supposed to be. The claim language reads on substituents, such as, nucleotides, sugars, proteins, etc. at every location of the molecule, for which there is no support in the specification. The nature and number of substituents permitted is not known. Therefore the metes and bounds of the compound could not be ascertained. Applicant's arguments have been fully considered but they are not persuasive because the metes and bounds of a claim should be known. It is understood that the inventive concept in the instant claims lies in the 7-membered lactone. However, all advances in the art are limited to minor modifications of the camptothecin structure such as substitutions on the camptothecin. The specification is limited to the substituents depicted on formula (B1) and (B2). The claims are broader than the broadest definition of the disclosure.

Without the recitation of all these substituents into the claims, the claims do not adequately define the instant invention. Applicants arguments in the brief filed 6/19/03 is directed to the 137 compounds made and tested. All of these compounds are substituted by substituents R<sub>2</sub>-R<sub>5</sub> as described in the specification. These compounds and their uses are

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allowable. It is unclear what else is intended because the claims are not limited to these but are of undeterminable scope.

Claims 18-23 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification is not adequately enabling for the scope of the compounds embraced by the claims.

All of the compounds made are drawn to a narrow group which does NOT give a reasonable assurance that all, or substantially all of them, are useful. The claims are not drawn in terms of a recognized genus but are directed to a more or less artificial selection of compounds.

There is no reason why a claim drawn in this way should not be limited to those compounds which are shown to be both new and useful. An Applicant is not entitled to a claim for the use of a large group of compounds merely on the basis of a showing that a selected few are useful and a general suggestion of a similar utility in the others.

Also, see *In re Surrey* 151 USPQ 724, regarding sufficiency of a disclosure for a Markush group, and MPEP 2164.03 for enablement requirements in cases directed to structure-sensitive arts such as the instant pharmaceutical arts. Note in *Surrey*, in which testing done on a group of homogeneous compounds having the same core was deemed NOT sufficient to support claims to various hetero groups of a much narrower range than is being claimed herein and located at only one position in the formula. The instant scope is enormous, in the billions of compounds, and therefore a few compounds within its scope is not remotely representative of such a scope. See MPEP 2164.03.

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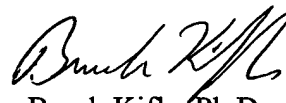
Applicants have no enabling disclosure to make compounds that are substituted at, say, the pyrrolidine or substituents adjacent to the oxygen on the lactone ring. The claims, however, embrace any and all substituents at these locations.

Claims 5-8 and 24 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruck Kifle, Ph.D. whose telephone number is 703-305-4484. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund J. Shah can be reached on 703-308-4716. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

  
Bruck Kifle, Ph.D.  
Primary Examiner  
Art Unit 1624

BK  
August 22, 2003